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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,834	12/20/2001	Ralph Lipp	SCH-1859	1489

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EXAMINER
YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/022,834	Applicant(s) LIPP ET AL.	
	Examiner Micah-Paul Young	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 3 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 6 contain the trademarks/trade names Gelva, TSR and Kollidon. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe polymerizing agents used in pressure-sensitive adhesives and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al (WO 96/40087) in view Lipp et al (USPN 5,676,968) or vice versa. The claims are drawn to a transdermal delivery system for delivering gestagens. The matrix of the transdermal delivery system is a polyacrylate adhesive, comprising copolymers of various acrylic monomers such as hydroxyethylacrylate and 2-ethylhexylacrylate. The matrix further comprises β-cyclodextrin as a crystallization inhibitor. The matrix also comprises penetration enhancers such as lauryl alcohol, and methyl esters.

Li et al teaches a transdermal delivery system where the matrix is a polyacrylate adhesive. The matrix is a copolymer of 2-ethylhexylacrylate and hydroxyhexylacrylate and further comprises estradiol and other gestagens (pg. 3, lin. 15 – pg. 4, lin. 12; examples). The reference however is silent to other components found common in the art, components such as stabilizers and penetration enhancers. These components are well known in the art, and would be incorporated in to any transdermal composition to improve the stability, performance and drug delivery of the formulation.

As seen in Lipp et al, which teaches a transdermal delivery of drugs, the formulation comprises stabilizers (crystallization inhibitors) such as N-vinylpyrrolidone products and derivatives like Kollidon® and dextrins such as β-cyclodextrin. The matrix of the reference is a polyacrylate adhesive that incorporates penetration enhancers such as lauryl alcohol, glycerol and urea (col. 2, lin. 4 – 67, examples).

While both references describe the transdermal delivery of gestagens in a polyacrylic adhesive matrix, neither specifically discloses the compound of applicant. The delivery of gestagens through polyacrylic adhesive matrices is well known in the art. It is the position of the examiner the compound of applicant is obviated by the prior art. The presence of the compound in a polyacrylic adhesive matrix is deemed non-critical to the patentability of the claimed invention, barring a showing of criticality to the specific compound of applicant and a showing of unexpected results.

With regard to claim 4, which recites a specific concentration of the gestagens, though the art does not disclose the specific compound, these limitations are also obviated by the prior art. Li, in combination with Lipp, provides a general transdermal polyacrylate adhesive formulation that delivers gestagens. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various pharmaceutical compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges

is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With this in mind one of ordinary skill in the art would have been motivated to follow the teachings and suggestions in the art. A skilled artisan would have included the penetration enhancers and stabilizers of Lipp into the formulation in order to reduce crystallization of the formulation and to improve the delivery of the active agents. A skilled artisan also could have been motivated to include the polymer matrix of Li in to the formulation of Lipp in order to provide a cohesive matrix for better delivery of the active agents. It would have been obvious to one of ordinary skill in the art, at the time of the invention to combine the teachings and suggestions as such with an expected result of transdermal delivery formulation with reduced crystallization and improved delivery of its gestagens.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cleary et al (USPN 4,906,463) teaches a transdermal delivery formulation for the delivery of gestagens such as estradiol.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MPY
October 2, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600